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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,443	09/02/2004	Ugur Sahin	16034US01	1542

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MCANDREWS HELD & MALLOY, LTD
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER

HALVORSON, MARK

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,443	Applicant(s) SAHIN ET AL.	
	Examiner Mark Halvorson	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 118-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 118-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/14/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 118-125 are pending and under examination.

Objections to Specification withdrawn

The objections to the specification are withdrawn in view of Applicant's amendments to the Specification.

- 35 USC § 112 2nd paragraph rejection withdrawn

The rejection of claims 118-125 for being indefinite is withdrawn in view of the amendment to claim 118.

35 USC § 112 1st paragraph rejection maintained

The rejection of claims 118-125 for failing to comply with the enablement requirement is maintained.

Applicants argue that Example 2 of the present application demonstrates that expression of TPTE mRNA is detectable in several cancer types, but not in normal, non-testis tissue. Applicants state that according to the specification, "the term 'disease' refers to any pathological state in which tumor-associated antigens are expressed or abnormally expressed."

Applicants arguments have been fully considered but are not persuasive. The term tumor antigen, broadly construed, encompasses antigens expressed in disease states other than cancer. Applicants have demonstrated that TPTE mRNA is overexpressed in a few cancer tissues. The specification only discloses that the expression of the nucleic acid of SEQ ID NO:19 is upregulated in over 30% of melanomas, prostate carcinomas, and bronchial carcinomas. (Table 2). There is no indication that there is an increase in protein expression in these tumors. Thus, the specification does not disclose that TPTE is overexpressed in all diseases as broadly claimed.

Applicants argue that TPTE protein is selectively expressed in testis and in a number of different tumors. However, it is not known whether the indicated "tumors" are cell lines or patient specimens. Further, the term "portion" in claim 1 is interpreted to encompass two amino acids which is insufficient to be detected by an antibody.

Furthermore, Applicants also argue that the instant specification provides examples of TPTE peptide complexed with an MHC molecule. Applicants argue that the specification further reports that "[t]he antigen ... showed *distinct colocalization with MHC I molecules located on the cell surface.*"

Applicants arguments have been fully considered but are not persuasive. The fact that the peptide was colocalized with MHC 1 molecules on the cell surface does not demonstrate that a peptide was in the binding groove of the MHC 1 molecule. Claim 125 reads on a peptide localized in the MHC 1 molecule binding groove. The specification does not provide any examples of any peptides that are complexed with an MHC molecule and induce an immune response. Considering the number of MHC molecules, the potential number of peptides encompassed by the claims and the lack of any information on the functional activity of the peptide complexed with a MHC 1 molecule, one of ordinary skill in the art would not know how to make and use the invention. The specification does not provide any working example of any peptide that would work with any MHC molecule in cancer, or any other disease. Considering the state of art, the broad scope of claims in respect to the nature of peptide and also to the nature of MHC molecules, it is concluded that undue experimentation is required to practice the claimed invention. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Summary

Claims 118-125 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/Misook Yu/
Primary Examiner, 1642